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TITLE: SPCR2 High Risk Suicidal Behavior in Veterans- Assessment of Predictors and Efficacy of Dialectical Behavioral Therapy

PRINCIPAL INVESTIGATOR: Marianne Goodman M.D.

CONTRACTING ORGANIZATION: Bronx Veterans Medical Research Foundation Inc.
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14. ABSTRACT

Approximately one third of the Army's completed suicides last year occurred in the post-deployment period (Alvarez 2009) highlighting the importance of studying high-risk suicidal veteran populations. This project proposes two related studies. The first project is a randomized clinical trial of 120 veterans identified with high-risk suicidal behavior comparing the efficacy of Dialectical Behavioral Therapy (DBT) vs. treatment as usual (TAU) on suicidal behavior as a primary outcome measure. A second aim of the project is to examine group differences between 150 veterans at high risk (HR) for suicide and 150 veterans at low risk (LR) in a variety of symptom domains. The goal of this will be to identify symptoms associated with suicidal behavior that may advise future treatment. Over the 41 months since study approval, 322 subjects have been consented and 293 baseline assessments were completed. 90 high-risk suicidal subjects have been randomized for the clinical trial and 44 have completed the six-month treatment trial. A no-cost extension for year 5 of the trial will allow us to recruit additional subjects for the treatment trial as we aim for 100 subjects total. We will easily meet recruitment goals of 300 for the baseline assessment. Our supplemental project on affective startle is meeting recruitment goals and we hope to begin final data analysis on baseline testing within the next 3 months. Thus far, the supplement has assessed 149 subjects at baseline and completed 14 6-month follow-ups. Post-treatment follow-up assessments will continue into next year.

15. SUBJECT TERMS- Borderline Personality Disorder, SUICIDE

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Introduction:

Approximately one third of the Army's completed suicides last year occurred in the post-deployment period (Alvarez 2009) highlighting the importance of studying high-risk suicidal veteran populations. This project proposes two related studies. The first project is a randomized clinical trial of 120 veterans identified with high-risk suicidal behavior comparing the efficacy of Dialectical Behavioral Therapy (DBT) vs. treatment as usual (TAU) on suicidal behavior as a primary outcome measure. A second aim of the project is to examine group differences between 150 veterans at high risk for suicide and 150 veterans at low risk in a variety of symptom domains. The goal of this will be to identify symptoms associated with suicidal behavior that may advise future treatment.

We will assess symptom domains including mood and substance use in our veteran population by comparing symptoms in low vs. high risk veterans recently discharged from the James J Peters VAMC (JJPVA) psychiatric inpatient unit. In addition, we will explore indices of interpersonal function and measure features that have some evidence of offering protection from suicide, which could be viewed as resilience factors. A particular emphasis of the present project is to characterize the nature of the interpersonal dysfunction in high risk individuals, as there exists very good evidence that social isolation, or a lack of a sense of "belonging" puts people at particularly high risk for suicide, in particular in a military sample . We intend to assess the impact of DBT vs. TAU on these symptom domains in addition to their impact on suicidal behavior.

Body:

In October 2011, a supplement to this project was approved to add a physiological measure, affective startle to the baseline assessment and post- DBT treatment.

Aim 1 relates to a randomized clinical trial of Dialectical Behavior Therapy (DBT) vs. treatment as usual (TAU) in 120 veterans recently hospitalized with high-risk suicidal behavior. This will be accomplished under the leadership of Dr. Marianne Goodman, James J. Peters VAMC, Bronx, NY 10468

Aim 1: To examine, in a randomized controlled trial (RCT), the efficacy of a 6 month treatment with standard DBT (weekly individual sessions, skills training group and telephone coaching as needed) as compared to TAU in 120 veterans recently discharged from an acute psychiatric inpatient stay with high risk suicidal behavior. The primary treatment outcome will be a quantification of suicidal events, as assessed by the Columbia Suicide Severity Rating Scale, which measures suicide attempts, plans and preparations. Our study will be powered to examine treatment assignment differences in this measure. Secondary outcomes will include suicidal ideation, parasuicidal events, treatment compliance, depressed mood, substance abuse and hopelessness.

This aims involves recruiting 120 veterans off the JJPVA "high-risk" suicide list; a designation made primarily after psychiatric inpatient admission for serious suicidal behavioral. High-risk

(HR) suicide subjects will undergo a comprehensive diagnostic interview prior to entering the treatment study. Subjects will receive 6 months of TAU vs. DBT but both groups will continue to receive standard psychopharmacology and case management services from their clinic providers. Subjects will receive a battery of assessments at month 6, 12 and 18.

Aim 2 relates to a comparison of high-risk and low-risk suicidal veterans in interpersonal functioning and resilience, in an effort to identify intermediate symptoms that are closely associated with HR suicidal behavior. This will be accomplished under the leadership of Dr. Marianne Goodman, James J. Peters VAMC, Bronx NY 10468

Aim 2: To recruit veterans recently discharged from an acute psychiatric inpatient stay comparing 150 veterans with HR suicidal behavior to 150 veterans without such behavior (LR) in symptom domains focusing on interpersonal functioning and resiliency.

Aim 3 is exploratory and examines the effect of treatment (DBT or TAU) on the putative intermediate symptom domains associated with HR suicidal behavior of interpersonal functioning and resiliency. This will be accomplished under the leadership of Dr. Marianne Goodman James J. Peters VAMC, Bronx NY 10468

Aim 3: To explore the effect of DBT on the candidate intermediate symptoms of interpersonal functioning and resiliency associated with HR suicidal behavior.

Promised work:
Parent Project-
The first 3 months is devoted to training the raters on our assessment and diagnostic battery while we await regulatory approvals. During months 3-6, we expect to perform thirty baseline assessments and 15 high-risk subjects will be randomized to treatment. During months 6-12, 12-18, 18-24, 24-30, we expect that thirty high-risk and thirty low-risk suicidal subjects will receive baseline assessments during each 6 month block. We anticipate that 25 of the high-risk subjects will proceed into treatment during each one of the time blocks. Months 30-36 will target 30 total additional assessments for baseline high and low-risk subjects with 5 of the HR individuals being randomized for treatment. The baseline assessment is a more comprehensive evaluation and we estimate that it will take approximately 6-7 hours with follow-up assessments requiring 1-2 hours.

While we met recruitment goals for Aim 1 of the study, our recruitment for the RTC fell behind. In order to continue recruitment we requested and were granted a fifth year, no cost extension. The Table below reflects promised work, and new numbers with a 5th year added.

	Baseline assessments (50% HR, 50% LR)	Randomized to treatment (HR only)	Follow-up assessments 6mo 12 mo 18mo
Months 0-3	-----	-----	----- ----- -----
Months 4-6	30	15	----- ----- -----
Months 7-12	60	25	12 ----- -----
Months 13-	60	25	19 11 ----

18			-		
Months 19-24	60	25	19	17	10
Months 25-30	60	25	19	17	15
Months 31-36	30 –	5 –	19	17	15
Months 37-48 (year 4)	**New year 4 target- 60** Actual 65 293 to date (goal 300)	**New year 4 target-25** Actual 15 90 to date (goal 120)	28	19	30
Months 49-60 (year 5)	**New year 5 target- 10** Recruitment just to meet RTC goals	**New year 5 target-10** 15	15	20	30

Progress to date Parent Study:

Towards accomplishing these aims, we received approval from our local IRB 7/9/09 and local Research and Development approval on 7/15/2009; prior to official funding of the project. This allowed us to *pilot* the intervention, assessments and randomization procedure. Dept of Defense approval was obtained on 4/27/2010; almost four months later that we had projected in our initial statement of work.

Recruitment for year #4
The study's recruitment has continued to be steady with **59** high risk (HR) subjects and **15** low-risk (LR) subjects signing consent between 9/29/12-9/30/13. Of the 59 HR consented subjects, 51 completed baseline assessments.15 LR subjects were consented over the past year and 15 of the 15 completed the baseline assessment. We are prioritizing HR recruitment in order to maximize flow through to the treatment trial.

For the treatment trial, **15** high-risk subjects were randomized during year 4. For the DBT arm: 21 subjects completed the 6 month trial, 20 have completed 12 month follow-up and 14 have completed the entire trial. For the TAU arm: there have been 23 patients who completed the 6-month trial and 21 completed 12 months. 16 have completed the entire trial.

These numbers are summarized below.

Overall recruitment since the study's inception includes:
203 high risk and **119** low risk consented with **190** completed high risk baseline assessments and **103** completed low risk baseline assessments. **90** subjects have been randomized in the treatment trial and **44** completed the 6-month treatment.

Summary of Year 4: 9/29/11-9/30/12 recruitment

	High Risk	*Low Risk*

# consented	59	15
# completed	51	15
# randomized	15	----------
#complete 6 month	13	----------
12 month f/up	11	----------
18 month f/up	6	----------

Summary of Entire Study to date

	High Risk	*Low Risk*
# consented	203	119
# completed	190	103
# randomized	90	----------
#complete 6 month	44	----------
12 month f/up	41	----------
18 month f/up	30	----------

Total: 293 of 300 completed baseline assessments
90 of 120 randomized to clinical trial

Progress Pertaining to Aim #1

Our Statement of work projected that by study completion we will have 300 baseline assessments finished. Currently we are at 293 and expect to achieve 300 by the end of this calendar year, easily completing this aim. Data analysis will proceed over year 5 along with manuscript generation. Interim analyses have yielded findings pertaining to the importance of Axis I diagnoses of substance abuse, Axis II diagnoses of borderline personality disorder and responses on the interpersonal psychological survey as important risk factors for identifying "high-risk" veterans (see **Figure 1**)**.**
The identification of the interpersonal psychological survey as a critical instrument has led us to further examine its contents through a computerized implicit task assessment that we will be piloting in year 5 (see **Figure 2**)**.**

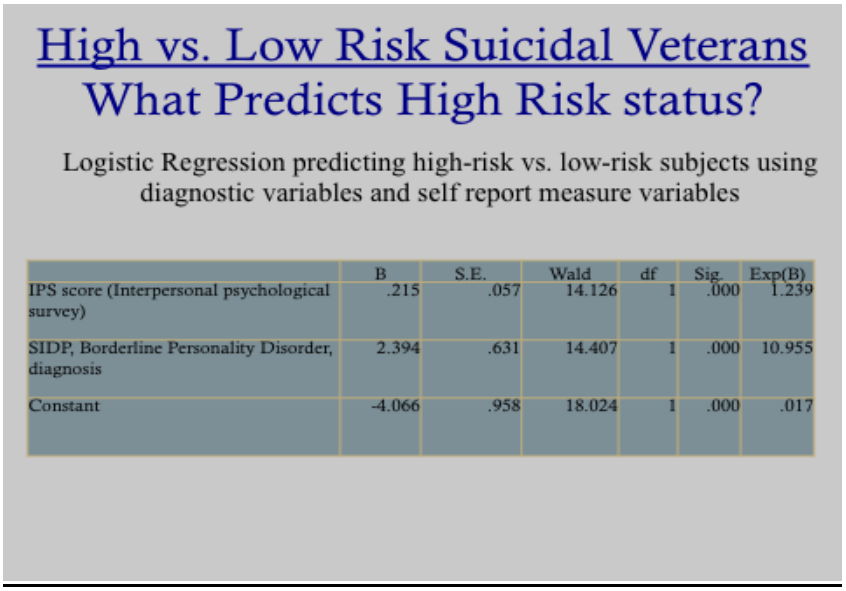


Figure 1- Predictors of Suicide Risk in Veterans

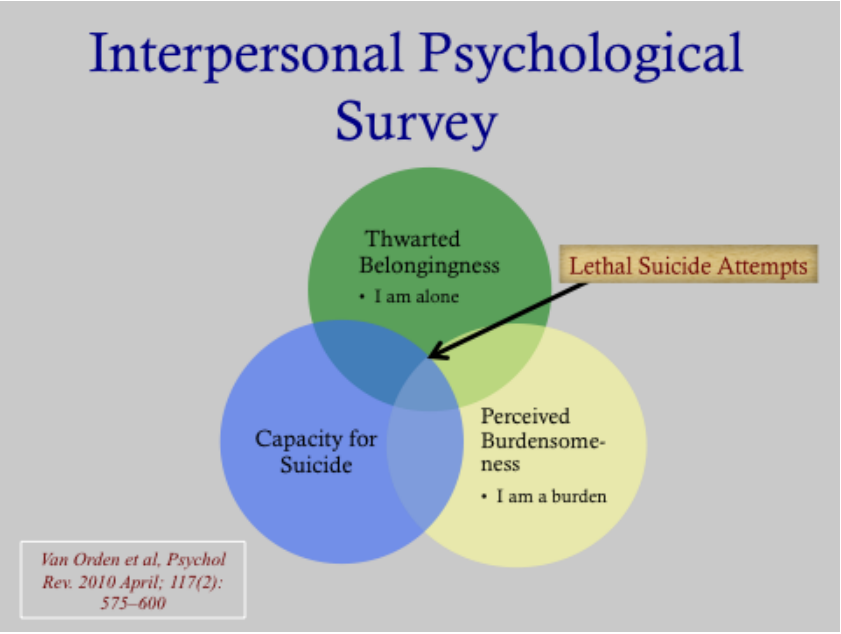


Figure 2- Interpersonal Psychological Survey components

Progress Pertaining to Aim #2

We have randomized 90 subjects to the treatment trial to date and are aiming to achieve 100 of the 120 promised. We continue to run subjects through the treatment trial and 1 year follow-up.

Progress Pertaining to Aim #3

This aim requires the completion of DBT treatment for multiple subjects and awaits year 5 of the study for adequate data to address. At present, all longitudinal data has been entered and we are planning on starting treatment trial data analysis fall-winter 2013.

Problems Accomplishing Tasks

With Hurricane Sandy this past year, the Manhattan VA hospital was closed for upwards of 5 months. This lead to disruptions of care at our facility, as Manhattan patients sought treatment temporarily at our hospital. This complicated RCT recruitment efforts as pts were less likely to enroll in a longitudinal study that would require changing the location of their outpatient care beyond the expected time of Manhattan VA's closure.

SUPPLEMENT:

In addition to our three aims for the parent study, we have two additional aims for the supplemental study:

Supplement Aim 1 is to conduct a nonverbal and objective psychophysiological assessment of emotion processing using the affective startle paradigm to test whether it might serve as a potential biomarker for differentiating levels of suicidality. This will be

accomplished under the leadership of Drs. Marianne Goodman and Erin Hazlett, James J. Peters VAMC, Bronx NY 10468

Aim 1. To examine the magnitude, time course, and rate of habituation of the startle eyeblink response during unpleasant, neutral, and pleasant pictures in 150 veterans with varying levels of suicidality; 60 veterans with a recent suicide attempt (during past 3 months), 60 veterans with suicidal ideation but no history of attempts, and 30 healthy veteran controls (i.e. no current psychiatric diagnosis).

This aim will be accomplished by adding the affective startle modulation paradigm to our current assessment battery of high- and low-risk suicidal subjects. Eligible subjects enrolled in the DoD funded parent project will participate in a 1-hour psychophysiology session at the MIRECC psychophysiology laboratory where we will record our primary variable of interest, namely the affective startle eyeblink response at baseline and 6 months for those enrolled in the DoD treatment trial. During this session, participants will view an intermixed series of unpleasant, neutral, and pleasant pictures from a standardized picture set. For each of the 3 picture conditions, we will examine three measures related to affective startle eyeblink modulation which is our psychophysiological measure of emotion processing: (1) the *amplitude* of the startle eyeblink response; (2) the *time course* of emotion processing by presenting the startle probes at different times during and post-picture processing; and (3) the rate of *habituation* of the startle eyeblink response.

Supplement Aim 2 is to compare startle variables across suicide groups (ideators, attempters) by presence or absence of borderline personality disorder to clarify if differences in affective startle modulation extend beyond personality disorder diagnosis. Thirty suicide attempters with BPD (SABPD+) will be compared with 30 suicide attempters without BPD (SABPD-) and 30 suicide ideators with BPD (SIBPD+) will be compared to 30 ideators without BPD (SIBPD-) across startle variables. This will be accomplished under the leadership of Drs. Marianne Goodman and Erin Hazlett, James J. Peters VAMC, Bronx NY 10468

Aim 2 investigates the relationship of Axis II diagnosis, suicidality and affective startle. The collected data for Aim 2 will be used to explore this question.

Supplement Aim 3 is exploratory and will examine whether (a) magnitude, time course and/or rate of habituation to unpleasant, neutral and pleasant pictures predicts treatment response to six-month Dialectical Behavioral Therapy (DBT) for suicidal behavior; and (b) magnitude, time course and/or habituation of affective startle improves with 6 months of DBT in treatment responders compared with non-responders.

We plan to study 150 veterans with varying levels of suicidality; 60 veterans with a recent suicide attempt (during the past 3-months), 60 veterans with suicidal ideation but no history of attempts, and 30 healthy veteran controls (i.e. no current psychiatric diagnosis) with a measure of psychophysiology. This aim will be accomplished by adding the affective startle modulation to our current assessment battery of high- and low-risk suicidal subjects. Eligible subjects enrolled in the DoD funded parent project will participate in a 1-hour psychophysiology session at the MIRECC psychophysiology laboratory where we will record our primary variable of interest, namely the affective startle eyeblink response. We will be testing whether affective startle is a biomarker of suicide risk and examining the effect of treatment on affective startle.

We will accomplish this by re-testing affective startle at 6-months for those enrolled in the DBT treatment arm.

Supplement Promised Work:

	Supplement: Startle assessments: Pt Baseline	Pt 6mo	HC Baseline	HC 6mo
Months 13-18	Obtain IRB approval			
Months 19-24	45	-----	12	----
Months 25-30	50	23 *	12	10
Months 31-36	25	22 *	6	11
Months 37-42	----	5 *	----	4
Months 43-48				

The project was awarded funding on 9/24/2011. In its first 12 months, the research team was incredibly effective in mobilizing resources and enrolling and testing **94** subjects at baseline and completing **1** 6-month follow-up. Over the most recent 12-month period (10/1/12 → 9/30/13), the team has been similarly effective with recruitment, testing an additional **55** subjects at baseline and **13** at 6-months following the treatment trial. These figures bring the cumulative total of baseline and 6-month numbers to **149** subjects and **14** subjects respectively. We therefore have almost completed baseline affective startle recruitment (149 of promised 150).

Progress Pertaining to Supplement Aim #1

Since receiving funding, we have run **149** patients at baseline and have done **14** 6-month follow-ups and therefore have met our recruitment goals for supplement Aim #1. The overall and 12-month breakdowns are as follows:

Group	Recruitment - Total	Recruitment – Last 12-Months
Controls	**32** (3F/29M)	**10** (1F/9M)
Ideators	**33** (1F/32M)	**13** (13M)
Single Attemptors	**34** (8F/26M)	**13** (2F/11M)
Multiple Attemptors	**50** (21F/29M)	**19** (9F/10M)
6-Month Follow-Up	**14** (2F/12M)	**13** (2F/11M)

Initial analyses on the first 40 subjects demonstrated a significant interaction between affective startle and suicide risk. (see **figure 3**). Multiple ideators, in the unpleasant picture condition, had significantly elevated affective startle % change values as compare to single attempters and ideators. We await confirmation of these exciting preliminary findings with the full data set.

Progress Pertaining to Supplement Aim # 2

See information pertaining to Aim #1.

Progress Pertaining to Supplement Aim # 3

We have assessed a total of 14 subjects with affective startle after six months of treatment.

Recruitment for this aim is dependent on successful completion of the parent RCT. We will continue to gather data for this aim over the duration of the treatment trial.

Problems Accomplishing Tasks

We are not experiencing any difficulty recruiting for this project and are in fact ahead of schedule. We expect to substantially increase the number of 6-month assessments in the coming year.

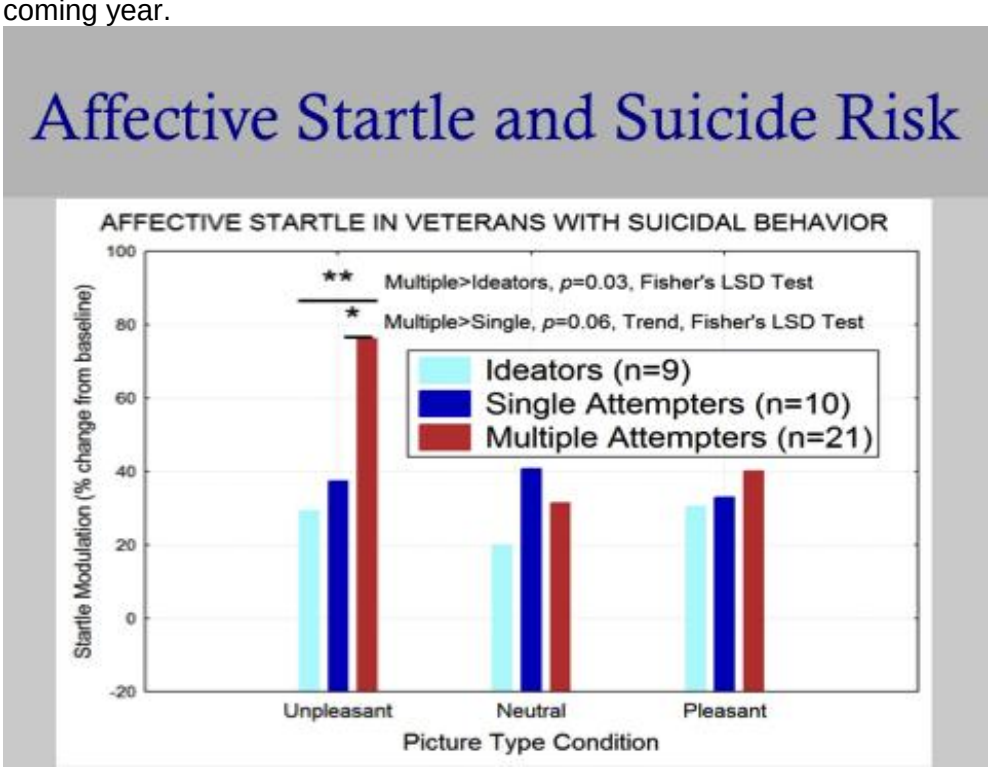


Figure 3- Affective Startle and Suicide Risk in veterans with ideation, history of single and multiple suicide attempts.

Key Research Accomplishments for both Parent and Supplement Projects

We have just completed year 4 of 5 for this study.

- In the 41 months since DoD IRB approval (4/27/10): recruitment has been brisk. **322** subjects have signed consent.
- **293** (out of promised 300) subjects completed baseline assessments.
- **90** HR patients were randomized to the treatment trial,
- **44** HR patients have completed the 6-month treatment trial, many are still in progress.
- **149 (**out of 150) subjects have completed baseline affective startle

Reportable Outcomes 2012-2013:

Conclusion:

Our preliminary baseline data highlights the importance of Axis II psychopathology, in particular, borderline personality disorder as a risk factor for high-risk suicidal behavior. This is relevant as the disorder is often under recognized in VA settings and not even listed in the Uniform Servics Package, the document listing required services for Veterans.
Additional data from the treatment trial, which has currently completed year 4 of 5 is needed before any conclusions can be drawn pertaining to the efficacy of dialectical behavioral therapy for high risk sucidality in veterans.

References:

Alvarez, V (2009). Suicides of Soldiers Reach High of Nearly 3 Decades New York Timescom. New York, New York Times.

Appendices: none included

Supporting Data: none included

Affective Startle Modulation in Suicidal Veterans

DMRDP Proposal Number WX81XWH-09-1-0722

PI: Goodman, Marianne Org: James J. Peters VAMC, Bronx NY 10468 Award Amount: $452,834

DMRDP

Study/Product Aim(s)

Aim 1 is to examine the magnitude, time course, and ratio of habituation of the startle eye blink response during unpleasant, neutral, and pleasant pictures in 150 veterans with varying levels of suicidality; 60 veterans with a recent suicide attempt (during past 3 months), 60 veterans with suicidal ideation but no history of attempts, and 30 healthy controls

Aim 2 is to compare startle variables across suicide groups (ideators, attempters) by presence or absence of borderline personality disorder to clarify if differences in affective startle modulation extend beyond personality disorder diagnosis. Thirty suicide attempters with BPD (SABPD+) will be compared with 30 suicide attempters without BPD (SABPD-) and 30 suicide ideators with BPD (SIBPD+) will be compared to 30 ideators without BPD (SIBPD-) across startle variables.

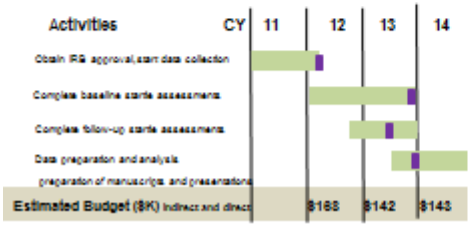
Aim 3 is exploratory and will examine whether (a) magnitude, time course and/or ratio of habituation to unpleasant, neutral and pleasant pictures predicts treatment response to six-month Dialectical Behavioral Therapy (DBT) for suicidal behavior, and (b) magnitude, time course and/or habituation of affective startle improves with 6 months of DBT in treatment responders compared with non-responders.

	Baseline assessments (50% HR, 50% LR)	Randomized to treatment (HR only)	Supplement: Startle assessments: Pt Baseline / Pt Assw / HC Baseline / HC Assw
Months 19-21	30	12-15	Obtain IRB approval
Months 21-24	30	12-15	25 ----- 12 -----
Months 25-30	60	25	50 12 * 12 10
Months 31-36	30	5	25 25 * 6 11
Months 37-42	-----	-----	---- 13 * ---- 4
Months 43-48	-----	-----	

* Only 1/2 of the randomized subjects will receive DBT

** We will also need to assess 30 healthy control veterans who are not included in the funded RCT study. These healthy controls will also participate in the affective startle paradigm both at baseline and 6 month follow up. We anticipate retaining 25 of the original 30 at the six-month follow-up. We anticipate recruitment of 2 control subjects a month over 1.5 years

Accomplishment: The supplement funding was not received until after month 24, five months later than the original target date. However, IRB approval was accomplished rapidly by month 26 and study recruitment commenced shortly afterward. We have currently assessed 149 baseline subjects and 14 6-month follow-up & maintaining a brisk recruitment rate. Data analysis is currently underway and we have already presented preliminary findings.



Updated: 10/2012

Goals/Milestones

CY11 Goal – obtain IRB approval, begin recruitment and assessment of subjects for baseline startle assessment

✓Assess 25 high risk and 12 healthy control subjects with startle paradigm by end of calendar year *(revised to 10 HR/6 LR due to 6 month delay in funding)*

CY12 Goals – ✓complete data collection of baseline startle assessments

✓Complete startle assessments of suicidal subjects (total n=100)

✓Begin to obtain 6 month follow-up startle

CY13 Goal – Complete data collection of 6 month startle assessments and data analysis (we have collected 149 of 150) ✓

☐Complete data collection on 6month follow up startle assessments (we have collected 14 to date)

✓prepare startle data for analysis and conduct analyses (in process)

☐Manuscript generation

☐Comments/Challenges/Issues/Concerns- n/a

Budget Expenditure to date

Projected Expenditure: $452,834 total Actual Expenditure: $153,925

High Risk Suicidal Behavior in Veterans - Assessment of Predictors and Efficacy of Dialectical Behavioral Therapy

DMRDP Proposal Number WX81XWH-09-1-0722

PI: Goodman, Marianne Org: James J. Peters VAMC, Bronx NY 10468 Award Amount: $1.279M

DMRDP

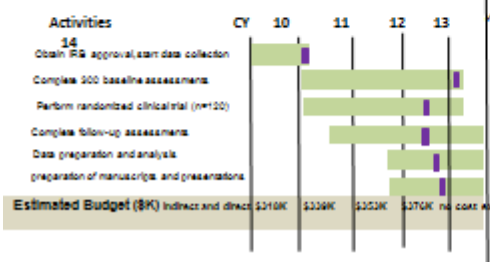
Study/Product Aim(s)

Aim 1: To examine, in a randomized controlled trial (RCT), the efficacy of a 6 month treatment with standard DBT (weekly individual sessions, skills training group and telephone coaching as needed) as compared to TAU in 120 veterans recently discharged from an acute psychiatric inpatient stay with high risk suicidal behavior. High-risk (HR) suicide subjects will undergo a comprehensive diagnostic interview prior to entering the treatment study. Subjects will receive 6 months of TAU vs. DBT but both groups will continue to receive standard psychopharmacology and case management services from their clinic providers. Subjects will receive a battery of assessments at month 6, 12 and 18.

Aim 2: To recruit veterans recently discharged from an acute psychiatric inpatient stay comparing 150 veterans with HR suicidal behavior to 150 veterans without such behavior (LR) in symptom domains focusing on interpersonal functioning and resiliency.

Aim 3: is exploratory and examines the effect of treatment (DBT or TAU) on the putative intermediate symptom domains associated with HR suicidal behavior of interpersonal functioning and resiliency.

Accomplishment: 329 subjects have signed consent. From this total, 292 subjects completed the baseline assessments. 90 subject have been randomized in the treatment trial which is ongoing. These data have generated 2 presentations and 4 posters to date with an addl submitted for 2014.



Updated: 1/2013

Goals/Milestones

✓CY10 Goal – obtain IRB approval, hire and train staff, begin recruitment targeting 90 baseline assessments and 40 randomized to treatment trial. Initial DoD IRB approval was delayed 5 months behind projected date. For the remainder of 2010, we completed 55 baseline assessments and randomized 23 high risk suicidal veterans for treatment.

✓CY11 Goal – continue data collection of baseline assessments (n~120) and randomization to clinical trial (n~50), and follow up assessments (n~76). Actual numbers were 96 consented subjects, 66 completed baseline assessments and 26 randomized to the tx trial.

✓CY12 Goal – continue data collection of baseline assessments (n~90) ✓ and randomization to clinical trial (n~30), and follow up assessments (n~102).

New CY 13 Goal- continue data collection of baseline assessments (n~75) and 50 subjects randomized to RTC by increasing efforts at our second recruitment site (Manhattan VAMC). Recruitment to date thru 2013- we have completed 292 baseline assessments and randomized 90 subjects to the treatment trial. Our recruitment for baseline assessments has increased due to addition of the second site, but clinical trial enrollment remains behind.

New CY 14 Goal- Complete data collection and data analysis & manuscript generation

Comments/Challenges/Issues/Concerns- recruitment for RCT as described above, addressed through addition of 5th year and no cost extension

Budget Expenditure to date Projected Expenditure: $1.279M Actual: (through9/13) $ 1.182M